

Appln No. 10/750,501
Amdt date September 11, 2006
Reply to Office action of May 11, 2006

REMARKS/ARGUMENTS

In the Final Rejection dated May 11, 2006, the Examiner rejected claims 25-27 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. In so rejecting, the Examiner asserts that the specification does not disclose that the ablation assembly has a generally straight distal region extending substantially tangentially to the generally circular curve of the ablation assembly. However, Applicant has amended the specification to recite that the generally straight distal region extends substantially tangentially from the generally circular main region. This amendment is supported by the original specification, claims and drawings. Specifically, the original specification notes that the generally straight distal region extends beyond the generally circular main region, as shown in FIG. 5. In addition, FIG. 5 illustrates the generally straight distal region extending substantially tangentially from the generally circular main region. Accordingly, no new matter is presented, and Applicant respectfully requests withdrawal of this rejection.

The Examiner also rejected claims 25-27 under 35 U.S.C. § 112, second paragraph as allegedly indefinite. In so rejecting, the Examiner asserts that the term "tangential" is indefinite because it is contextual. However, as used in the claims of this application, the term "tangential" is used in connection with the term "generally circular curve." Given this context, one of ordinary skill in the art would certainly recognize that the term "tangential" is meant to describe the orientation of the extending object relative to the circular object. Accordingly, Applicant respectfully requests withdrawal of this rejection.

The Examiner also maintained the rejection of claims 13-16, 19-22 and 25 under 35 U.S.C. § 102(e) as allegedly anticipated by Stewart, et al. (U.S. Patent No. 6,325,797). In maintaining this rejection, the Examiner admits that Stewart fails to disclose "contacting the inner circumference of the tubular region with at least a portion of the outer circumference of the generally circular curve.," as recited in independent claims 1, 13, 22 and 25. However, the Examiner appears to assert that "anatomical differences throughout a population" account for such a discrepancy. Applicant respectfully disagrees.

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Stewart teaches contacting the *outer* circumference of the pulmonary vein, and expressly teaches away from ablating within the pulmonary vein. Specifically, Stewart notes that ablation of the tissue within the pulmonary vein may undesirably cause the vein to shrink or constrict. In addition, Stewart notes that such ablation within the pulmonary vein may cause stenosis due to the relatively small diameter of the vein. Also, Stewart notes that ablation of tissue within the pulmonary vein may result in undesirable damage to other vital bodily structures located adjacent to the pulmonary vein. Column 2, lines 22 to 29. Given these concerns, Stewart discloses forming lesions in the left atrial wall *about* the pulmonary vein ostium. Column 2, line 30 through Column 3, line 26. As such, the invention disclosed in Stewart is specifically designed to treat tissue *outside* the pulmonary vein, contrary to the Examiner's assertion that the Stewart device can be used to ablate an inner circumference of the pulmonary vein.

In addition, despite the Examiner's assertion to the contrary, Stewart fails to disclose that the generally straight distal region extends "substantially tangentially to the generally circular curve of the main region," as recited in independent claim 25. As noted above, one of ordinary skill in the art would recognize that the term "tangential" describes the orientation of the generally straight distal region relative to the generally circular main region. Accordingly, independent claims 1, 13, 22 and 25, and all claims dependent therefrom, including claims 2-12, 14-16 and 19-21, are allowable over Stewart.

The Examiner also maintained the rejection of claims 1-5, 8-16 and 19-27 under 35 U.S.C. § 102(e) as allegedly anticipated by both Koblish (U.S. Patent No. 6,745,080) and Bowe, et al. (U.S. Patent No. 6,771,996). In rejecting the claims over Koblish, the Examiner asserts that Koblish discloses "rotation in clockwise and counterclockwise manners corresponding to pushing and pulling." Office action, pp. 2-3. However, Koblish discloses only the rotation of a stylet within a catheter body to wind and unwind the helical portion of the distal member. There is no rotation of the catheter, as recited in independent claims 1 and 22. Column 9, lines 65-66.

Similarly, the Examiner asserts that Bowe discloses the rotation of the ablation assembly. However, Bowe simply notes that "[u]sing a marker allows for the mapping catheter and the ablation catheter to rotate relative each other." Column 13, lines 2-4. Bowe does not disclose

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rotation of the catheter to facilitate ablation. In fact, once positioned in the desired area for ablation, Bowe fails to disclose any rotation. Rather, Bowe simply states that "energy is then applied to the ablation electrode system to ablate the tissue around the ostium to thereby form a circumferential lesion." Column 14, lines 31-36. Accordingly, independent claims 1 and 22, which both recite rotation of the catheter, and all claims dependent therefrom, including claims 2-12 are allowable over Koblish and Bowe. In addition, claim 26, which also recites rotation of the catheter body, is also allowable over Koblish and Bowe.

Koblish and Bowe also fail to teach or suggest that "the tip electrode has an exposed region, at least a portion of which has an outer diameter greater than the outer diameter of the flexible tubing of the ablation assembly," as recited in independent claim 13. As such, independent claim 13, and all claims dependent therefrom, including claims 14-16 and 19-21, are allowable over Koblish and Bowe.

Also, Koblish and Bowe fail to teach or suggest that the ablation assembly also has "a generally straight distal region extending substantially tangentially to the generally circular curve of the main region," as recited in independent claim 25. Although Koblish appears to disclose an anchor member extending beyond the distal member, the anchor member does not extend substantially tangentially from the helical portion of the distal member. Bowe similarly fails to disclose a generally straight distal region extending substantially tangentially from the generally circular curve of the main body. Accordingly, independent claim 25, and all claims dependent therefrom, including claims 26 and 27, are allowable over Koblish.

Moreover, like Stewart, Bowe fails to teach or suggest "contacting the *inner* circumference of the tubular region with at least a portion of the outer circumference of the generally circular curve," as recited in independent claims 1, 13, 22 and 25. Rather, Bowe discloses positioning the ablation system "around the ostium," indicating that the ablation occurs on the *outer* circumference of the pulmonary vein. Column 14, lines 31-36.

The Examiner also rejected claims 1-12, 17-20, 23, 24, 26 and 27 under 35 U.S.C. § 103(a) as allegedly obvious over Stewart in view of Bowe. However, neither Stewart nor Bowe disclose "contacting the *inner* circumference of the tubular region with at least a portion of the

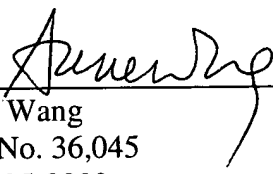
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outer circumference of the generally circular curve," as discussed above. Accordingly, independent claims 1, 13, 22 and 25, and all claims dependent therefrom, including claims 2-12, 17-20, 23, 24, 26 and 27, are allowable over Stewart and Bowe.

Finally, the Examiner rejected claims 1-22 and 25-27 under the judicially created doctrine of obviousness type double patenting as allegedly unpatentable over claims 1-20 of U.S. Patent No. 6,733,499. In that regard, Applicant submits herewith a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c). Applicant therefore respectfully requests withdrawal of this rejection.

In light of the above remarks, Applicant respectfully submits that all of pending claims 1-22 and 25-27, as amended, are in condition for allowance. Accordingly, Applicant respectfully requests a timely indication of allowance. However, if there are any remaining issues that can be addressed by telephone, Applicant invites the Examiner to contact the undersigned at the number indicated below.

Respectfully submitted,
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